MR# 337624

~~MR# 337474~~

August 5, 2011 **This Report CONTAINS Confidential Business Information**

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CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

8EHQ - 08 - 17209

SUBJECT: TSCA 8(e)SUBMISSION

Dear Sir or Madam:

( ) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns ( ), an experimental pyrethroid insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is .

has imported for R&D on behalf of (" ").

The following reports concerning have been submitted to your agency: Two acute oral toxicity studies with rats (November 15, 2007: 8EHQ-07-16995 & 16996); a preliminary development toxicology study with rats (January 7, 2008: 8EHQ-08-17027); a micronucleus study with rats (February 19, 2008: 8EHQ-08-17081); an acute inhalation toxicity study in rats (July 11, 2007: 8EHQ-08-17209); a two week oral toxicity study in dogs (October 9, 2008: 8EHQ-08-17297); a micronucleus study with rats (February 16, 2010: 8EHQ-10-17866): an in-vivo unscheduled DNA synthesis (UDS) assay in rat hepatocytes (April 5, 2010: 8EHQ-10-17907); effects on pre- and postnatal development, including maternal function in rats (May 21, 2010: 8EHQ-10-17958); an in-vivo unscheduled DNA synthesis (UDS) assay in female rat hepatocytes (May 21, 2010: 8EHQ-10-17957); an acute oral toxicity study in rats (August 26, 2010); and a thirteen week repeated dose oral (feeding) toxicity study in Wistar rats (8EHQ-10-18166).

recently learned of new toxicological effects in an acute inhalation toxicity study in rats. An outline of the study follows:

Acute Inhalation Toxicity Study of in Rats

was administered to Crl:CD(SD) rats (5 animals/sex/dose) at dose levels of 500, 1000 and 2000 mg/m^3 in a single inhalation of four hours by nose-only at a dust aerosol. The mean actual aerial concentrations were chemically 583, 1110 and 2030 mg/m^3. In the clinical observation, tremor of tail, tremor, hypersensitivity, muscular rigidity, urinary incontinence, ataxic gait and tip toe gait were noted. These clinical signs disappeared within four days after exposure.

believes that the clinical signs observed in this study are reportable under TSCA 8(e).

Performing Laboratory:
[May we provide the lab name?]

Study methods:
Animals: Crl:CD(SD) rats, males and females, 11 weeks old at the start of administration, 5 rats/group/sex
Administration route and periods: nose-only inhalation, single for 4 hours
Dose levels: 500, 1000, 2000 mg/m^3 (analyzed chamber concentration: 583, 1110, 2030 mg/ m^3)
Particle size: MMAD; 5.00, 3.73, 4.86 μm, GSD; 2.76, 3.14, 2.56
Observation items: Clinical signs, body weights, and necropsy
Body weight (at the time of an exposure start): 410-456 g (Male), 247-295 g (Female)

Results:
Mortality: One female of the 2000 mg/m^3 group died.
Clinical signs: Besides the clinical signs described above, wet fur, scab and stains (around eyes and nose) were observed.
Body weight, Gross pathology: No treatment-related changes were observed
LC_{50} value: Males and Females; greater than 2030 mg/kg

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm 's efforts to commercialize this compound. Please refer to the attached letter of March 17, 2010 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( ).

Yours sincerely,

Technical Consultant

Encl.
cc: